PROSPECTIVE, RANDOMIZED COMPARISON OF PROSEAL LMA AND ENDOTRACHEAL TUBE IN ADULT WOMEN SELECTED FOR ELECTIVE LAPAROSCOPIC GYNAECOLOGICAL SURGERY

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MADRAS MEDICAL COLLEGE,
CHENNAI -600 003.

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CERTIFICATE

This is to certify that the dissertation entitled, **"PROSPECTIVE, RANDOMIZED COMPARISON OF PROSEAL LMA AND ENDOTRACHEAL TUBE IN ADULT WOMEN SELECTED FOR ELECTIVE LAPAROSCOPIC GYNAECOLOGICAL SURGERY"** Submitted by **Dr.G.POONKUZHALI** in partial fulfillment for the award of the degree of Doctor of Medicine in Anesthesiology by the Tamilnadu Dr.M.G.R. Medical University, Chennai is a bonafide record of the work done by her in the Department of Anesthesiology, Madras Medical College, during the academic year 2007 -2010.

Dr.J.MOHANASUNDARAM
M.D, DNB, PhD
DEAN,
MADRAS MEDICAL COLLEGE
&GOVT. GENERAL HOSPITAL,
CHENNAI – 600 003.

PROF Dr.C.R.KANYAKUMARI
M.D., D.A
PROFESSOR & H.O.D,
DEPT OF ANAESTHESIOLOGY,
MADRAS MEDICAL COLLEGE,
CHENNAI – 600 003.

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INTRODUCTION

Dr. Archie Brain developed a new way of linking artificial and anatomical airway, between 1981 and 1987.This new concept called Laryngeal Mask Airway combined the advantages of a non invasive facemask and the more invasive tracheal tube.

Originally LMA was recommended as a better alternative to the face mask. But ever since its development the LMA has challenged the assumption that tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation.

Though LMA provided all the above advantages, the risk of gastric distension, pulmonary aspiration of gastric contents and fear of inadequate ventilation acted as a deterrent to the widespread use of LMA.

To overcome the above complications, Dr. Archie Brain designed the Proseal Laryngeal Mask Airway (PLMA) in 2000, with modifications designed to enable separation of gastro intestinal and respiratory tract, improve airway seal, enable positive pressure ventilation and diagnose mask displacement. A Drain tube (DT) enables diagnosis of mask misplacement, reduces risk of gastric insufflation, regurgitation, and aspiration of gastric contents.

Laparoscopic surgery or more appropriately minimal access surgery is well established since last 2 decades. It is the advances in anaesthesia and laparoscopic instrumentation and techniques that have led to remarkable development in the field of gynaecological surgeries.

General anaesthesia with controlled ventilation remains the gold standard technique recommended for laparoscopic surgeries. Endotracheal tube was the preferred technique for GA, but few complications do arise with ETT.

PLMA is the new airway device that forms a more effective glottic seal and it facilitates passage of a gastric tube. It probably provides protection against regurgitation and prevents gastric insufflation when correctly placed.

With this background this study was conceptualized to compare Endotracheal tube and Proseal LMA for elective laparoscopic gynaecological surgery.

AIM OF THE STUDY

To compare the advantages and disadvantages of PLMA and Endo Tracheal Tube (ETT) for General Anaesthesia in women coming for elective laparoscopic gynaecological surgery.

PROSEAL LMA

The Proseal laryngeal mask airway was designed and developed by Dr.Archie Brain in late 1990, with a primary goal to construct a laryngeal mask with improved ventilatory characteristics and that also offered protection against regurgitation and gastric insufflations.

DEVICE DESCRIPTION:

The Proseal LMA is made from medical grade silicone and is reusable. It has four main components

1. Mark
2. Inflation line with pilot balloon.
3. Airway tube
4. Drain tube

The cuff of the mask has identical proportions but different dimensions amongst sizes.

Modified Feature	Intended Purpose
1) The second cuff attached to dorsal surface	To improve seal by pushing the ventral cuff.
2) The ventral cuff that is larger proximally	To form a better seal by plugging gaps in the proximal pharynx.
3) A large conical shaped distal cuff	To form a better seal with the hypopharynx. To reduce the risk of down folded epiglottis obstructing the distal aperture.
4) A parallel, narrow-bore, double tube configuration	To increase stability To improve seal by allowing the tongue to form a more effective plug.

5) A flexible, wire reinforced airway tube	To prevent airway tube from kinking.
6) A drainage channel	To facilitate gastric tube insertion. To divert regurgitated fluid away from the respiratory tract. To prevent gastric insufflation.
7) A drainage tube distal aperture that is sloped anteriorly.	To allow the deflated tip to form a fine edge for insertion.
8) A plastic supporting ring around the distal drainage tube.	To prevent the drainage tube from collapsing when the cuff is inflated.
9) Drainage tube that passes within the bowel.	To avoid altering the external shape of the cuff. To function as mark aperture bar for accessory vent.
10) A rectangular depression in the proximal bowel tube	To function as an accessory ventilation channel. To prevent pooling of secretions at the distal aperture of the airway.
11) Built-in-bite block	To prevent airway obstruction. To prevent damage to the device during biting. To provide information about depth of insertion. To help fuse airway and drainage tube

		together.
12)	Introducer strap	To prevent finger from slipping off the tube. To keep proximal cuff in the midline.
13)	No back plate	To reduce and allow room for the dorsal cuff.
14)	No mask aperture bar	To reduce resistance to gas flow.

SIZES AVAILABLE

Proseal LMA size	***Patient selection Guidelines***	***Proseal LMA airway tube ID(mm)***	***Maximum cuff inflation Volume (Air)***	***Gastric Tube***	***ETT***	***FOD***
1 ½	5-10 kg	6.4	7ml	10 Fr	4.5	3.5
2	10-20 kg	6.4	10ml	10 Fr	4.5	3.5
2 ½	20-30 kg	8.0	14ml	14 Fr	4.5	3.5
3	30-50 kg	9.0	20ml	16 Fr	5.0	4.0
4	50-70 kg	9.0	30ml	16 Fr	5.0	4.0
5	70-100 kg	10.0	40ml	18 Fr	5.0	5.0

These are maximum volumes that should never be exceeded. It is recommended that the intracuff pressure should not exceed 60cm H_2O

Protocol for PLMA Use:

Preparation of Use:

With proper cleaning, sterilization and handling, the proseal LMA can be safely used 40 times.

CLEANING:

It is washed in warm water and dilute (8-10% w/w) sodium bicarbonate solution until all visible foreign matter is removed. Clean the tubes using a small soft bristle brush. Thoroughly rinse the cuff, airway tube and drain tube in warm, flowing tap water to remove cleaning residues. Care should be taken to ensure that water does not enter the device through the valve.

STERILIZATION:

Steam autoclaving is the only recommended method for sterilization of the proseal LMA. Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backwards to obtain a high vaccum. The maximum temperature should not exceed 135°C or 275°F. The proseal LMA introducer and cuff deflator should be cleaned and sterilized in the same manner.

PERFORMANCE TESTS:

Non-clinical tests must be conducted before each use of the device. These include,

1. Visual Inspection:

Ensure that the thin-walled section of the drain tube lying within the mask bowl is not torn or perforated. Do not use the proseal LMA if the tubes are discoloured as this impairs the ability to see foreign particles or regurgitated fluids. Examine the surface of the device for damage.

2. Inflation and deflation:

Using a syringe fully deflate the device so that the cuff walls are tightly flattened against each other. Do not use if the cuff walls re-inflate immediately and spontaneously.

Inflate the cuff from complete vacuum with 50% more air than the recommended

maximum inflation volume. Any tendency of the cuff to deflate within 2 minutes indicates the presence of a leak. Examine the symmetry. Inspect the interior of the drain tube.

While the device remains 50% over-inflated examine the inflation pilot balloon for damage.

PRE-INSERTION PREPARATION:

Prior to insertion, the cuff should be fully deflated to a flattened wedge shape. This shape facilitates atraumatic insertion and correct positioning in the patient. It reduces the risk of entry of the distal end into the vallecula or glottis and avoids it becoming caught against the epiglottis or the arytenoids.

METHODS OF CUFF DEFLATION:

It includes

- Using original silicone LMA proseal cuff deflator
- Manually by compressing the distal end between finger and thumb.

Lubrication of posterior surface of the cuff with water soluble lubricant like K-J jelly should be performed just before insertion to prevent drying of the lubricant.

INDEX FINGER INSERTION TECHNIQUE:

- Finger insertion technique is not recommended for proseal LMA sizes 1½ - 2½. These sizes have a dedicated introducer.
- Hold the proseal LMA like a pen with the index finger pushed into the introducer step.
- Under direct vision, press tip of the cuff upwards against the hard palate and flatten the cuff against it.

- As the index finger passes further into the mouth finger, joint begins to extend.

The jaws should not be held widely open.

- Push the jaw downwards with middle finger or instruct the assistant to pull lower jaw downwards momentarily using the index finger to guide the device, press downwards towards the other hand, exerting counter pressure.

- Advance the device into hypopharynx until a definite resistance is felt. Full insertion is not possible unless the index finger is fully extended and wrist is fully flexed.

- Before removing the finger, the non-dominant hand is brought from behind the patients head to press down on the airway tube.

This prevents the device from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point the proseal LMA should be correctly located with its tip firmly pressed up against the upper oesophageal sphincter. Remove the finger.

DEVICE INFLATION:

After insertion, the tubes should emerge from the mouth directed caudally. Without holding the tubes, inflate the cuff with just enough air to obtain an intracuff pressure equivalent to approximately 60cm H_2O. During cuff inflation, do not hold the tube as this prevents the mask from settling into its correct location.

The signs of correct placement may include one or more of the following:

- Slight outward movement of tube upon inflation.

- Presence of smooth oval swelling in the neck around the thyroid and cricoid area. Never over inflate the cuff.

DEVICE FIXATION:

Once inflated, the device should be fixed in place with fish mouth taping (maxilla to maxilla). While fixing, ensure that the tip of the mask is pressed securely against the upper oesophageal sphincter. Correct fixation is more critical for PLMA because any migration proximally of the tip from hypopharynx will result in air leakage up the DT during IPPV.

PROBLEMS WITH PLMA PLACEMENT & APPROPRIATE CORRECTIVE MANEUVRES

- An inadequate depth of anaesthesia may result in coughing and breath holding during insertion. Should this occur, anaesthesia should be deepened immediately.

- If the patient's mouth can not be opened sufficiently to insert the mask, first ensure that the patient is adequately anaesthetized. An assistant can be asked to pull the jaw-downward.

- The cuff must press against the palate throughout the insertion manaeuvre; otherwise the tip may fold back on itself or impact on an irregularity or swelling in the

posterior pharynx (eq. Hypertrophied tonsil). If the cuff fails to flatten or begins to curl over as it is advanced, it is necessary to withdraw the mask and reinsert it.

TESTS FOR PLACEMENT:

1. Depth of insertion:

It has been observed that when most of the bite block was outside the patient's mouth, PLMA was frequently malpositioned. For women, mean depth of insertion has been found to be 18.6cm and for men 20.9cm.

2. Test for Obstructed Airway:

Unobstructed placement of PLMA is demonstrated by manual ventilation with rise and fall of the chest and square ware capnograph and normal compliance of reservoir bag.

3. Soap Bubble Test:

This is done to evaluate the seal with GIT. Non-toxic soap solution is used to create a membrane over DT tip. Any leak during IPPV will dislodge the membrane.

Uses:

1. Confirms PLMA location behind cricoid cartilage.
2. Confirms zero leak at PLMA - Oesophageal seal
3. Detects negative DT pressure and aerophagia with spontaneous ventilation.
4. Diagnoses oesophageal insufflation during IPPV.

4. Lubricant Jelly Test:

It evaluates seal with GIT 0.5 to 1ml of lubricant jelly is placed in the proximal end of the DT to seal it. If there is a leak from the DT, the bolus of jelly is blown off.

5. Suprasternal notch tap test:

This is used to determine whether the leading edge of PLMA lies behind the cricoid cartilage. A non toxic soap solution is placed across the proximal end of DT creating a membrane. The suprasternal notch is the gently tapped. A pulsating soap membrane with tapping confirms the tip location behind cricoid cartilage.

6. Gastric Tube placement test:

When there is no leak up the DT, then insertion of gastric tube is attempted via DT without using much force. This gives information about the DT patency which is mandatory for safe use of PLMA.

OROGASTRIC TUBE INSERTION:

The primary function of the drain tube is to provide a separate conduit from and to be alimentary tract. This is then passed down the DT of PLMA without any haste or force. A slight resistance is normal felt as the tip passes against upper oesophageal sphincter. There is an inherent resistance to gastric tube insertion after 23cm of passage due to angulation of 9^0 in the passage of DT to its tip. There may be difficulty in passing gastric tube due to following reasons.

1. Selection of too large gastric tube
2. Inadequate lubrication
3. Use of cooled gastric tube
4. Cuff over inflation
5. Malposition of PLMA

The advantages of inserting gastric tube are

1. It allows removal of gas or fluid from the stomach
2. Confirm position/ Patency of drainage tube
3. Functions as a guide to PLMA insertion if accidental displacement occurs.

The disadvantages of inserting gastric tube are

1. Risk of tracheal placement

2. Oesophageal perforation rarely
3. The presence of gastric tube may trigger regurgitation by interfering with oesophageal sphincter function.
4. Gastric tube blocks drainage tube so that gas and fluid can not escape from oesophagus.

TEST FOR DT AIRLEAK AND PATENCY

Air leak

Large volume leaks are detected by listening over drainage tube or feeling the air with hand. Small volume air leaks are detected best by placing water based lubricant or soap bubble over the end of drain tube.

TESTS FOR PATENCY

1. Passage of gastric tube
2. Passage of fibreoptic scope
3. Supra sternal notch tap test.

REVIEW OF LITERATURE

Proseal LMA, a variant of the classic LMA offers certain distinctive advantages. It offers better seal, better inflation pressure and the ability to decompress the stomach by passing a gastric tube through the drain tube.

The literature was searched and reviewed for using PLMA / ETT in laparoscopic gynaec surgery.

HOHLRIEDER M, BRIMACOMBE J, ESCHERIZHUBER S, ULMER H,

KELLER C et al IN 2007

Compared Proseal LMA with endotracheal tube on postoperative analgesia requirements following gynaecological laparoscopic surgery.

One hundred female patients, ASA I/II aged 18 - 75 yrs were studied. Anaesthesia management was identical for both groups and included induction of anaesthesia using propofol / fentanyl and maintenance with propofol / remifentanyl, muscle relaxation with rocuronium, IPPV, gastric tube insertion, dexamethasone / tropisetron for antiemetic prophylaxis, and diclofenae for pain prophylaxis.

All types of postoperative pain were treated using intravenous patient controlled analgesia (PCA) morphine.

They found that pain scores were lower for the PLMA at 2 hrs and 6 hrs but not at 24 hrs. Morphine requirements were lower for PLMA by 30.4%, 30.6%, and 23.3% at 2, 6 and 24 hrs respectively. They concluded that postoperative pain is lower for PLMA than endotracheal tube in females undergoing gynaecological laparoscopic surgery.

HOHLRIEDER M, BRIMACOMBE J, VON GOEDECKE A, KELLER C et

al IN 2007

Assessed postoperative nausea, vomiting, airway morbidity and analgesic requirements for PLMA and ETT in 200 female patients, ASA I & II, aged 18 - 75 yrs undergoing breast and gynaecological surgery.

Ventilation was better and airway trauma less frequent for PLMA. For PLMA time spent in postoperative care unit was shorter (69 Vs 88 mt $P<0.001$). Few doses of tropisetron ($P <$ or $= 0.001$) required in postoperative care unit. Nausea was less frequent at all times (Over all 13%Vs 53%, $P = 0.001$) vomiting was less frequent at 2 hrs (4% Vs 18%, $P = 0.003$) and 24 hrs (5% Vs 19%, $P = 0.004$) and sorethroat was less frequent at all times (Over all 12% Vs 38%, $P < 0.0001$).

They concluded that the frequency of postoperative nausea, vomiting, airway morbidity and analgesic requirements are lower for PLMA when compared to endotracheal tube.

3. MILLER DM, COMPOROTA L, et al IN 2006

Compared the efficacy of PLMA and SLIPA supra laryngeal airways (SLA) with standard tracheal tube in 150 patients undergoing day care laparoscopic gynaecological surgery requiring general anaesthesia.

An identical GA technique was used in all patients apart from the addition of muscle relaxants and reversal drugs in ETT group. Ease of use, quality of seal, ventilation, systolic pressure, response to intubation, side effects and operating room time were assessed.

Both PLMA and SLIPA were easy to insert (100% success) and ventilation with respective maximum sealing pressures of 31 and 30cm H_2O ($P = 0.4$) with no muscle relaxants. The seal quality is both PLMA and SLIPA permitted the use of low flows, 485 (291) and 539 (344) ml x min (-1) ($P = 0.2$) respectively, although in the ETT group significantly lower flows (377 (124 ml x min (-1) ($P < 0.01$) were achieved.

Systolic pressure in the SLA group was more stable in response to insertion than in ETT gp with PLMA, there was a lower incidence of sorethroat than with ETT gp (30% vs 57%) ($P < 0.05$) and less difference with SLIPA (30% vs 49%) ($P > 0.05$).

With both SLA there was a significant reduction in operating room time (> 3mts) ($P < 0.001$).

The concluded that PLMA (reusable) and SLIPA (Single use) SLA's were easy to use without requiring muscle relaxants and less operating room time compared to tracheal tube in day care laparoscopies.

4. PIPER SN, TRIEM JG, ROHM KD, MALECK WH, SCHOLLHORN TA, BOLDT J, et al IN 2004.

Assessed the practicality of PLMA when compared to ETT in 104 patients undergoing gynaecological laparoscopic surgery. TIVA was performed by the same anaesthetist. They measured MAP, HR, circuit pressure at 2 measurement points and incidence of coughing and sorethroat.

There was no difference between PLMA and ETT concerning circuit pressure at any measurement points. At the end of anaesthesia MAP (92 +/– 13 vs 100 +/– 14 mmHg; $P < 0.001$) and HR (66 +/– 13 Vs 76 +/– 14 beats/mt; $P < 0.01$) were lower in the PLMA gp compared to ETT gp. 25 patients of ETT group coughed at the end of anaesthesia but nobody in PLMA group ($P < 0.00001$). There was no difference with regard to postoperative sorethroat. The insertion of PLMA was easier compared to

ETT ($P < 0.05$), but they found no significant difference concerning insertion times.

Finally they concluded that PLMA is a convenient and practical approach for anaesthesia in patients undergoing laparoscopic surgery.

5. GIUSEPPE NATALINI MD, GABRIELLA LANZA MD, ANTONIO ROSANO MD, et al IN 2002

Compared the frequency of airway seal and sorethroat with PLMA and std. LMA in 60 adults, ASA I, II & III patients undergoing laparoscopic surgery under GA with controlled ventilation (Tidal volume 7ml/Kg, PEEP - 10cm H_2O)

HR, BP, inspiratory and expiratory tidal volume, airway pressure, $EtCO_2$ and SpO_2 were recorded. Leak fraction was calculated as the difference between inspiratory and expiratory tidal volume divided by inspiratory tidal volume. Postoperative sorethroat frequency was scored in the recovery room (early) and 1 week after surgery (Late).

Leak fraction was $7 \pm 3\%$ with LMA and $7 \pm 4\%$ with PLMA
($P = 0.731$). Frequency of sorethroat is mild in 13% and 10% of patients with LMA and PLMA respectively during the recovery room stay.

Hence they concluded that PLMA and LMA show similar airtight efficiency and sorethroat evaluation performed in recovery room appears as reliable as later evaluation.

6. N.R.EVANS, SV. GARDNER ET AL IN 2002

Assessed insertion characteristics, airway seal pressure, haemodynamic response to insertion, ease of gastric tube placement, gastric insufflation and post op. Sorethroat in 300 anaesthetized adults.

Insertion was successful in 94% of patients and graded as easy in 91% of patients. There was no difference in ease of insertion or success rate with either introducer or finger insertion method. Mean airway pressure was 29 cm H_2O and 20% of patients had seal pressure >40 cm H_2O. Gastric tube placement was successful in 98.6% of patients. There was no haemodynamic response to insertion. Sorethroat was noted in 16% of patients after 24 hours. Hence they concluded PLMA was a reliable supraglottic airway device that gives an effective seal.

7. J.ROGER MALTY, MICHAEL BERIAULT ET AL

In 2002 compared PLMA with endotracheal tube with respect to pulmonary ventilation and gastric distension during laparoscopic cholecystectomy. 109 patients undergoing laparoscopic cholecystectomy were randomized to receive PLMA or

ETT.

Ventilatory parameters and gastric distension were noted in both groups. There was no statistically significant difference in $SpO_2/EtCO_2$ between both groups. Change in gastric distension during surgery was similar in both groups. Hence they concluded correctly placed PLMA or ETT provided equally effective ventilation without clinically significant gastric distension.

8. G.NATALINI, M.E FRANCESCHETTI et al IN 2003

They compared PLMA with LMA in obese patients. The study was conducted on 60 obese patients randomized to receive mechanical ventilation through PLMA or LMA. Airway cuffs were inflated to 60cm H_2O. Controlled ventilation with 10cm H_2O of PEEP was applied. If leak fraction was >15%, intra cuff volume was increased. Intra cuff volume needed to be increased in 45% of patients in LMA group compared to 13% in PLMA group. Leak fraction in PLMA group was 6% which was comparable to tracheal group.

Hence they concluded that PLMA was a better airway device for morbidly obese patients compared to LMA.

9. J.ROGER MALTBY, MICHAEL T. BERIAULT, NEIL C. WATSON, et al 2003

They compared LMA - C and LMA - Proseal with ETT with respect to pulmonary ventilation and gastric distension in 209 women, aged 18 years and above, ASA I-III, BMI > $30kg/m^2$ undergoing gynaecological laparoscopy.

Anaesthesia was induced with propofol, fentanyl and succinyl choline or rocuronium. Intubated with LMA-C 4 size in non obese individuals and size 4 or 5 PLMA in obese patients. In the ETT group, they used 7.0mm ETT in all patients. Anaesthesia was maintained with isoflurane in nitrous oxide and 30-50% oxygen, fentanyl and neuro muscular blockade with mechanical ventilation (TV-10ml/kg).

There were no statistically significant differences between LMA-C/PLMA and ETT groups for SpO_2, $EtCO_2$ or airway pressure before, or during peritoneal insufflation in short or long periods of peritoneal inflation. Differences between groups with respect to stomach size changes during surgery were not statistically significant.

Concluded correctly placed LMAC/PLMA is as effective as an ETT for IPPV without significant gastric distension in non-obese and obese individuals.

DETAILS OF STUDY

1. OFFICIAL TITLE

Prospective, Randomized, study of Proseal LMA as an effective alternative to endotracheal intubation for laparoscopic gynaecological surgery.

2. OBJECTIVE

To evaluate the effectiveness of Proseal LMA over endotracheal tube.

3. STUDY DESIGN

Prospective, Randomized, Comparative single blinded case control study.

4. STUDY TYPE

Interventional.

5. STUDY SETTING AND POPULATION

After obtaining Institutional Ethical committee clearance and patient's written informed consent, the study was carried out in AOT, Kasthurba Gandhi Hospital, Institute of Social Obstetrics, Chennai from January 2009 to February 2009.
The study was conducted in 50 female patients in the age group of 18 years and above belonging to ASA I and II Posted for elective laparoscopic gynaecological surgery.

6. ELIGIBILITY

1.	Age	:	18 years and Above
2.	Gender	:	Female
3.	Weight	:	BMI < 30kg/m^2
4.	ASA I & II.		

7. INCLUSION CRITERIA

- ❖ Adult women coming for elective laparoscopic gynaecological surgery.
- ❖ Age - 18 years and above
- ❖ ASA I & II
- ❖ Who had given valid informed consent
- ❖ Mallampatti Scores I & II only

8. EXCLUSION CRITERIA

- ❖ Severe cardiovascular, Hepatic and Renal disease
- ❖ Patients with difficult airway
- ❖ BMI >30 kg/m^2
- ❖ History of Gastro Oesophageal Reflux disease

- ❖ History of Hiatus Hernia
- ❖ Nil per oral for 6 hrs

9. MATERIALS REQUIRED

- ❖ Endotracheal tube 7, 7.5 ID sizes
- ❖ Proseal LMA 3 size
- ❖ Macintosh laryngoscope
- ❖ Stop clock
- ❖ 10ml syringe

10. STUDY OUTCOME

- ❖ Ease of Intubation
- ❖ Tissue taken for intubation
- ❖ Success rate
- ❖ Number of attempts for successful placement
- ❖ BP, HR, SPO_2 changes to intubation
- ❖ $EtCo_2$ changes
- ❖ Gastric Distension
- ❖ Airway trauma
- ❖ Post op awareness like sorethroat
- ❖ Post op breathing difficulty like laryngospasm

EASE OF INTUBATION

The ease by which the patient was intubated judged subjectively.

SUCCESS RATE:

Patient could be intubated or not, and if intubated in how many number of attempts.

TIME TAKEN FOR INTUBATION

It was measured from proseal LMA or endotracheal tube introduced into the patient's oral cavity until confirmation of proper positioning of proseal LMA / ET tube.

GASTRIC DISTENSION

It was measured by gynaecologist who was operating, gynaecologist was asked about gastric distension just before peritoneal deflation. Gynaecologist's judgement was measured in an ordinal scale from 0 – 10. (0 = empty stomach and 10 = distension of stomach that interfered surgical field.

11. METHODOLOGY

Ethical committee approval

↓

Patients satisfying inclusion criteria

↓

Informed consent obtained

↓

Randomization by closed envelope method

↓

Proseal LMA Study Group – Endotracheal tube study group

↓

Pre medication

↓

Pre oxygenation

↓

Induction

↓

No Bag and Mask Ventilation

↓

Intubation

↓

Measurement of outcome

↓

Data compilation

↓

Statistical Analysis

↓

Conclusion

CONDUCTION OF STUDY

The patients who had come for laparoscopic gynaecological surgery screened for co morbid illness and difficult airway. Age, Height and Weight were assessed. If patients satisfied inclusion criteria, informed consent was obtained and the patients were randomized in to 2 groups using closed envelope technique as proseal LMA group and endotracheal tube group. After the patient was shifted inside the operating room, intravenous assess gained. ECG monitor, Pulse oximeter and non-invasive Blood pressure monitors were connected. Preoperative BP, HR and SpO_2 were recorded.

Patient was premedicated with Inj. Glycopyrrolate 0.2mg and Inj. Fentanyl 2 µg/kg. Pre oxygenated with 100% oxygen at a flow rate of 8L/mt by using tight fitting facemask for 5 mts. Patient was induced with Inj.2% Lignocaine Hydrochloride (Xylocard) 1.5mg/Kg, Inj. Propofol 2mg / Kg & Inj. Suxamethonium 2 µg/Kg. Bag and mask ventilation was avoided between induction and intubation. Pre intubation BP, HR, and SpO_2 were recorded. One minute after giving Inj. Suxamethonium, 3 Size proseal LMA was inserted in sniffing position by using index finger insertion technique. Cuff was inflated with 20ml room air to the manufacturers recommended cuff pressure of 60cm H_2O before anaesthetic circuit was connected and patient's lung are ventilated. Position of PLMA was confirmed by bilateral chest movement, Square EtCO2 waveform and silent epigastrium by stethoscope auscultation.

With the PLMA, we filled the proximal 3 cm of the drain tube with the water soluble lubricant jelly, if a gas bubble rose through the jelly during inspiration indicating a gas leak into the oesophagus, we corrected the position of PLMA and repeated the test until no bubble appeared.

In the Endotracheal tube group, by using Macintosh laryngoscope, we inserted 7.00/ 7.5mm ID tube in all patients and inflated the cuff until no leak was audible during manual ventilation.

A gastric tube was not passed prophylactically in either group. (No gynaecologist requested passage of gastric tube to deflate the stomach in any patients)Post intubation BP, HR, SpO_2 and $EtCO_2$ were recorded. Time taken for insertion, Ease of intubation and number of attempts were also recorded.

Anaesthesia was maintained with 1 MAC sevoflurane/ Halothane and N_2O: O_2 at 2:1 ratio. Muscle relaxation was maintained with Inj.Atracurium 0.5mg/Kg. Post intubation BP, HR and SpO_2 were recorded at 3 mts and 5 mts interval.

Gynaecologist was requested to initiate the surgical procedure. Trendelenberg tilt # 15* was provided at the gynaecologist's request. Pneumo peritoneum was created with CO_2 gas and intra abdominal pressure was maintained $\leq$ 15mmHg. $EtCO_2$ was recorded after peritoneal inflation. The gynaecologist was requested to look for gastric distension and to grade it in an ordinal scale measuring from 0 – 10. (0 = empty stomach; 10 = distension of stomach that interfered surgery) $EtCO_2$ was

recorded after peritoneal deflation.

After completion of surgery and adequate neuromuscular recovery patient was reversed with Inj. Neostigmine 50µg/kg and Inj. Glycopyrrolate 0.4mg. Before extubation a sterile suction catheter was passed through the drainage tube and gastric contents was drained out. After thorough oral suction cuff was deflated and patient was extubated.

Blood staining in the airway, cough, laryngospasm / Stridor, sorethroat, and the need for airway intervention during emergence form anaesthesia were recorded.

Once the recovery was found adequate, patient was shifted to post operative ward and patients were interviewed for next 24 hours regarding cough, sorethroat and laryngospasm.

OBSERVATION AND RESULTS

This prospective, randomized, comparative, single blinded case control study compares PLMA insertion with endotracheal tube in 50 adult females undergoing elective laparoscopic gynaecological surgery.

All data were collected, tabulated and expressed as Mean +/– standard deviation. Appropriate statistical analysis was conducted. All quantitative data were compared using unpaired student's test. All qualitative data were compared using Chi square test. P values were calculated for all tests. A P values 0 to 0.01 was considered as 1% significant, 0.011 to 0.05 was considered as 5% significant, and >0.05 was considered as not significant.

The summated results are presented below.

EASE OF INTUBATION

Group	***Easy***		***Difficulty***		
	No	***%***	***No***	***%***	
PLMA	24	96	1	4	P = 0.312 Not significant
ETT	25	100	0	0	

The ease by which the patient was intubated judged subjectively.

By using PLMA, 24 cases were intubated easily and one was intubated with difficulty. By using ETT, all 25 cases were intubated easily.

Since it is a qualitative data values are compared by using Chi square test. Statistical analysis do not reveal any difference (P = 0.312).

NUMBER OF ATTEMPTS FOR SUCCESSFUL PLACEMENT

Group	***Attempt-I***	***Attempt – II***	***Mean***	***Standard Deviation***	
PLMA	21	4	1.16	0.374	T=2.14 P =0.038 Significance 5%
ETT	25	0	1.0	0.0	

Successful placement of PLMA is defined by the following criteria

1. Square wave pattern on capnography
2. No airleak over mouth, stomach, draintube
3. Positive suprasternal notch tap test.
4. Effective ventilation (TV > 8ml/Kg, $EtCO_2$ <45 mmHg).

PLMA insertion was successful in 21/25 cases in first attempt while 4 patients 4/25 required second attempt. With ETT all 25 patients were intubated in first attempt.

Statistical analysis reveals P value of 0.038 which is significant up to 5% which may be due to small sample size and lack of experience with PLMA.

TIME TAKEN TO INTUBATE

Group	***Mean***	***Standard Deviation***	
PLMA	37.36	21.07	t=1.13 P =0.265 Not Significant
ETT	32.4	6.212	

The time taken for PLMA/ETT from introduction into oral cavity to the final confirmation of its proper positioning.

Time taken for intubation with PLMA is 37.36 and with ETT is 32.4.

Student's t test reveals P value of 0.265 which is not significant. This indicates there is no difference in intubation time between PLMA and ETT.

GASTRIC DISTENSION

Group	***Mean***	***Standard Deviation***	
PLMA	0.56	1.227	t=1.42
ETT	1.08	1.352	P =0.161 Not Significant

Gastric distension was measured by gynaecologist who was operating. It was measured just before peritoneal deflation in an ordinal scale from 0 – 10.

Gastric distension with PLMA is 0.56 and ETT is 1.08. Student's 't' test reveals P value of 0.161 which is not significant. This indicates that PLMA provides good airway seal and adequate pulmonary ventilation.

SPO_2 CHANGES

	Groups	***No***	***Mean***	***Standard Deviation***	
Pre Op	PLMA	25	99.8	0.50	t=2.25 P =0.804 Not Significant
	ETT	25	99.8	0.62	
Pre intubation	PLMA	25	99.92	0.28	t =0.59 p=0.561 Not significant
	ETT	25	99.96	0.20	
Post Intubation 1 mt	PLMA	25	99.96	0.20	t=0.45 P =0.657 Not Significant
	ETT	25	99.92	0.40	
Post Intubation 3 mt	PLMA	25	99.96	0.20	t=1.17 P =0.248 Not Significant
	ETT	25	99.84	0.47	
Post Intubation 5 mt	PLMA	25	99.92	0.28	t = 0.59 P =0.561 Not Significant
	ETT	25	99.96	0.20	

SPO_2 was measured pre operatively, just before intubation, 1mt, 3mt and 5mt after intubation. The actual values are documented in the tabular column above. Statistical analysis by students t test reveals P value of 0.804, 0.561, 0.657, 0.248 and 0.561 respectively which are not significant.
Hence there was no significant oxygenation difference between two techniques.

$ETCO_2$ CHANGES

	Groups	***No***	***Mean***	***Standard Deviation***	
Post intubation	PLMA	25	29.2	2.08	t = 0.18 P =0.861 Not Significant
	ETT	25	29.08	2.71	

After peritoneal inflation	PLMA	25	30.44	2.58	t = 1.16 P =0.251 Not Significant
	ETT	25	29.56	2.77	
After peritoneal deflation	PLMA	25	34.32	3.85	t = 0.78 P =0.441 Not Significant
	ETT	25	33.36	4.83	

$EtCO_2$ was recorded after intubation, after peritoneal inflation with CO_2 and after peritoneal deflation. The actual values are documented in the tabular column. Student's t test reveals P value of 0.861, 0.251 and 0.441 respectively which are not significant.
This indicates that PLMA provides good pulmonary ventilation.

BLOOD STAINING IN AIRWAY

Group	***Yes***	***No***	***Mean***	***Standard Deviation***	
PLMA	1	24	1.96	0.2	t=0.59 P =0.561 Not Significant
ETT	2	23	1.92	0.28	

Blood staining in the airway noted after extubation which indicates airway trauma.

It occurred in 1/25 cases with PLMA and 2/25 cases with ETT. Chi square test reveals P value of 0.561 which is not significant.

Hence incidence of airway trauma is same in both the groups.

POST OPERATIVE AIRWAY MORBIDITY

	Groups	***Yes***	***No***	***Mean***	***Standard Deviation***	
Sore Throat	PLMA	1	24	1.96	0.200	t=1.41 P =0.161 Not Significant
	ETT	4	21	1.84	0.374	
Laryngo Spasm	PLMA	0	0	2.00	0.0	Not significant
	ETT	0	0	2.00	0.00	

Post operative sorethroat and laryngospasm were assessed for 24 hours post operatively.
Sorethroat occurred in 1/25 cases with PLMA and 4/25 cases with ETT.
Laryngospasm did not occur in both the groups. Through documented data are clinically relevant stastical analysis reveals P Value of 0.164 which is not significant.
Hence incidence of post operative airway morbidity is same in both the groups.

HAEMODYNAMICS

HEART RATE

	Groups	***No***	***Mean***	***Standard Deviation***	
Pre Op	PLMA	25	96.8	20.01	t = 0.92 P =0.363 Not Significant
	ETT	25	92.4	13.13	
Pre Intubation	PLMA	25	98.56	16.98	t = 1.21 P =0.232 Not Significant
	ETT	25	92.96	15.71	
Post Intubation 1 mts	PLMA	25	98.68	17.42	t = 0.65 P =0.518 Not Significant
	ETT	25	101.92	17.74	
Post Intubation 3 mts	PLMA	25	92.6	19.71	t = 1.77 P =0.083 Not Significant
	ETT	25	102.24	18.74	
Post Intubation 5 mts	PLMA	25	87.04	14.85	t = 1.72 P =0.091 Not Significant
	ETT	25	95.00	17.68	

SYSTOLIC BLOOD PRESSURE

	Groups	***No***	***Mean***	***Standard Deviation***	
Pre Op	PLMA	25	127.08	12.36	t = 0.30 P =0.766 Not Significant
	ETT	25	126.08	11.2	
Pre Intubation	PLMA	25	121.04	12.63	t = 0.85 P =0.401 Not Significant
	ETT	25	124.20	13.72	
Post Intubation 1mt	PLMA	25	114.28	18.23	t = 2.30 P =0.026 Significant 5%
	ETT	25	127.60	22.50	
Post Intubation 3 mts	PLMA	25	111.08	18.20	t = 3.20 P =0.002 Significant 1%
	ETT	25	130.52	24.28	
Post Intubation 5 mts	PLMA	25	103.20	14.73	t = 2.93 P =0.005 Significant 5%
	ETT	25	117.68	19.83	

DIASTOLIC BLOOD PRESSURE

	Groups	***No***	***Mean***	***Standard Deviation***	
Pre Op	PLMA	25	80.04	8.56	t = 1.16 P =0.250 Not Significant
	ETT	25	77.04	9.64	
Pre Intubation	PLMA	25	77.6	9.88	t = 1.20 P =0.236 Not Significant
	ETT	25	74.08	10.84	
Post Intubation 1mt	PLMA	25	71.8	15.97	t = 2.14 P =0.037 Significant 5%
	ETT	25	81.32	15.44	
Post Intubation 3 mts	PLMA	25	72.16	16.53	t = 2.44 P =0.019 Significant 5%
	ETT	25	83.60	16.68	
Post Intubation 5 mts	PLMA	25	64.64	15.11	t = 2.24 P =0.030 Significant 5%
	ETT	25	75.36	18.61	

MEAN ARTERIAL PRESSURE

	Groups	***No***	***Mean***	***Standard Deviation***	
Pre Op	PLMA	25	95.7	8.53	t = 0.94 P =0.352 Not Significant
	ETT	25	93.36	9.11	
Pre Intubation	PLMA	25	92.04	9.94	t = 0.43 P =0.668 Not Significant
	ETT	25	90.75	11.26	
Post Intubation 1mt	PLMA	25	85.94	15.38	t = 2.33 P =0.024 Significant 5%
	ETT	25	96.72	17.22	
Post Intubation 3 mts	PLMA	25	85.14	16.45	t = 1.89 P =0.064 Not Significant
	ETT	25	95.62	22.24	
Post Intubation 5 mts	PLMA	25	77.46	14.23	t = 2.56 P =0.014 Significant 5%
	ETT	25	89.42	18.54	

Heart rate, systolic blood pressure Diastolic blood pressure and mean arterial pressure were measured pre operatively, pre intubation, 1mt, 3mt and 5mts after intubation. The actual values are documented in the tabular column.

Statistical analysis by students t test reveals significant blood pressure changes 1mt, 3mt, and 5mts after intubation and no significant difference in heart rate between two techniques.

Hence there was a significant haemodynamic response with ETT when compared to PLMA.

DISCUSSION

The Proseal LMA provides an acceptable way to maintain a clear airway and provide positive pressure ventilation. It is also associated with reduced risk of gastric insufflation, regurgitation and aspiration of gastric contents.

This study was designed to evaluate the effectiveness of PLMA when compared to ETT with respect to pulmonary ventilation and gastric distension during gynaecological laparoscopy.

This study was conducted in 50 adult women, ASA I & II, aged 18 years and above undergoing elective laparoscopic gynaecological surgery (both short and long duration procedure).

EASE OF INTUBATION

1. Miller DM, camporota L, et al in 2006 compared PLMA and SLIPA with ETT in 150 patients. Both PLMA and SLIPA were easy to insert (100% success) and ventilate with maximum sealing pressure of 30cm H2o (P = 0.4) with no muscle relaxant.

The findings of our study are in concurrence with the above data. Both ETT and PLMA were intubated with ease with P value of 0.312.

2. N.R. Evans, S.V. Gardner et al in 2002 assessed insertion characteristics of PLMA, airway seal pressure, ease of gastric tube placement in 300 anaesthetised patients.

Insertion was successful in 94% of patients and graded as easy in 91 % of patients. Gastric tube placement was successful in 98.6% of patients.

In our study 96% of patients (24/25) were graded as PLMA with ease.

NUMBER OF ATTEMPTS TO SUCCESSFUL PLACEMENT

1. Miller DM, Camporota L, et al in 2006 compared PLMA with ETT in 150 anaesthetised patients. PLMA was easy to insert in all patients with 100% success rate and was easy to ventilate.

In our study, we compared PLMA and ETT in only 50 anaesthetised patients. Sample size is very minimal (33% only). Possible reasons for disparity in numbers of attempts for successful placement may be small sample size and lack of experience.

2. N.R.Evans, S.V. Gardner et al in 2002 assessed insertion characteristics of PLMA in 300 anaesthetised patients. Insertion was successful in 94% of patients.

If we compare the sample size with the above study, sample size in our study in 16.6% only. This again supports the disparity in our results.

TIME TAKEN FOR INTUBATION

1. Miller DM, Camporota L, et al in 2006 compared PLMA, SLIPA with ETT in 150 anaesthetised patients undergoing day care laparoscopic gynaecological surgery. They concluded PLMA ands SLIPA were easy to use and less operating room time (P = < 0.001) was required compared to ETT in day care laparoscopies.

In our study no significant difference (P = 0.265) in intubation time between PLMA and ETT. This disparity may be due to small sample size.

GASTRIC DISTENSION

1. J.Roger Maltby, Michael T, Beriault et al 2003, compared PLMA with ETT in 209 women undergoing laparoscopic gynaecological surgery in both short and long procedures. They concluded no statistically significant difference between PLMA and ETT with respect to stomach size changes.

This result in comparable with our study (P = 0.161).

2. J.Roger Maltby, Neil C, Watson et al in 2002, Compared PLMA with ETT in 109 patients undergoing laparoscopic cholecystectomy. They concluded that no significant gastric distension in both the groups. This study result is comparable with our study which shows P value of 0.161.

PULMONARY VENTILATION

1. J. Roger Maltby, Michael T. Beriault, compared PLMA and ETT in 209 women undergoing laparoscopic gynaecological surgery, concluded no statistically significant difference between PLMA and ETT groups for SpO_2, $EtCO_2$ before or during peritoneal insufflation in short and long period of peritoneal inflation.

This result is comparable with our study result which shows no significant SpO2 change (P = 0.804, 0.561, 0.657, 0.248, 0.561) measured Pre op, Pre intubation, 1mt, 3mt and 5mts after intubation and there were no significant $EtCO_2$ changes (P = 0.861, 0.251, 0.44) measured after intubation, after peritoneal inflation and after peritoneal deflation.

2. J.Roger Maltby, Michael Beriaul et al in 2002 compared PLMA and ETT in 109 patients undergoing laparoscopic cholecystectomy concluded no statistically significant difference in SpO_2 / $EtCO_2$ between two groups.

This result is comparable with our study.

BLOOD STAINING

1. Brimacombe Joseph, Keller C et al in 2004, In their study on 240 patients, concluded that there was no significant airway morbidity and visible blood staining on PLMA.

This is in concurrence with our study which also shows blood staining in 1/25 cases with PLMA and 2/25 cases with ETT with a P value of 0.561 (not significant)

POST OPERATIVE AIRWAY MORBIDITY

1. Miller DM, Camporota. L, et al in 2006 in their study on 150 patients, concluded that lower incidence of sorethroat with PLMA than with ETT group (30% Vs 57% and P value < 0.05).

This result in comparable with our study result which shows 1/25 Vs 4/25, P = 0.164.

2. Hohlrieder M, Brimacombe J, et al in 2007 compared PLMA with ET in 200 female patients, concluded that less frequency of sorethroat with PLA (12% Vs 38%, P <0.001). This result is comparable with our study.

HAEMODYNAMICS

1. Miller DM, Camporota L, et al in 2006, compared systolic pressure which was more stable with PLMA in response to insertion than with ETT.

This result is comparable with our study which shows significant systolic blood pressure values (P=0.026,0.002,0.005) 1mt,3mts and 5mts after intubation respectively, diastolic blood pressure values (P 0.037, 0.019, 0.30) 1mt, 3mt and 5mts after intubation and mean arterial pressure changes (P = 0.24, 0.14) 1mt and 5mts after intubation.

2. Piper SN, Triem JG, Rohmkd et al in 2004 compared PLMA and ETT in 104 patients, concluded high MAP with ETT (92 +/- 13 Vs 100 +/- 14mmHg;P < 0.01) and lower HR with PLMA (66+/-13 vs 76 +/- 14 beats/ mt; P < 0.01).

This result is comparable with our study, which shows high MAP 1mt, 3mts, and 5mts after intubation (P = 0.24, 0.14), no significant HR values (P = 0.518, 0.083, 0.091) 1mt, 3mts, and 5mts after intubation.

SUMMARY

This Prospective, Randomized, Comparative single blinded case control study evaluate the effectiveness of PLMA over ETT in 50 adult women, ASA I & II, aged 18 years and above undergoing elective laparoscopic gynaecological surgery (Short and long duration) under GA with IPPV.

The conclusions deduced from the study are:

1. Both PLMA and ETT were intubated with ease (P = 0.312)

2. First attempt success rate with PLMA and ETT was 21/25 and 25/25 patients respectively. Second attempt success rate with PLMA was 4/25 statistical analysis shows 5% significance may be due to small sample size.

3. Both the techniques had comparable and insignificant difference in intubation time (P = 0.265).

4. No significant gastric distension intra operatively with both PLMA and ETT. No gynaecologist requested passage of gastric tube to deflate the stomach intra operatively. So PLMA provides good oropharyngeal seal and pulmonary ventilation.

5. Both the techniques had no significant difference in SpO_2 and $EtCO_2$ before and during peritoneal insufflation. So PLMA is also a good airway device for laparoscopic surgery.

6. Blood staining on PLMA and ETT was comparable and was not statistically significant.

7. Post operative sorethroat and laryngospasm were not statistically significant in both the groups.

8. Haemodynamically there was significant difference between two groups with regard to systolic blood pressure, diastolic blood pressure and mean arterial pressure and PLMA was found to be a better device than ETT in this aspect.

Hence PLMA is an excellent alternative airway device to endotracheal tube in laparoscopic surgery.

CONCLUSION

The Proseal LMA is an excellent alternative airway device to ETT in laparoscopic gynaecological surgery with respect to ease of intubation, time taken for intubation, number of attempts for successful placement, gastric distension, pulmonary ventilation, Blood staining of airway and Post operative airway morbidity and a better device with respect to Haemodynamic response

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PROFORMA

DATE :

ROLL NO:_____

AIRWAY DEVICE USED : .....

Name:

Age : **Sex: Female**

IP no :

DOA : **DOS:** **DOD:**

Wt : **Ht :** **BMI:**

Diagnosis:

Surgical Procedure Done:

PRE OPERATIVE ASSESMENT:

A. HISTORY:

- **Comorbid illness and treatment details:**
- **Effort Tolerance: ……METS**
- **H/O any documented difficult Airway:**
- **H/O Previous surgeries/ lap surgeries:**

B. GENERAL EXAMINATION:

Anaemia: **Jaundice:**

BP: **Pulse:**

CVS: **RS:**

C. AIRWAY EXAMINATION:

- **Gross alteration in airway anatomy:**
- **Neck Flexion:**

(can touch manubrium sterni with chin ~ 25 to 30 degrees)

- **Neck Extension:**

(can see the ceiling without raising the eyebrows)

- **Inter Incisor Distance:……cm**
- **Thyro mental distance : …….cm**
- **Upper Lip Bite Test:**
- **Dentures:**

Yes	No

If Yes it is Removable / Fixed :

- **Buck teeth:**
- **Loose tooth:**
- **Absent teeth:**
- **Modified Mallampatti Score:**

D. MEASURES OF STUDY OUTCOMES:

- **Intubation response:**

	Pre Op	Pre intubatio	Post intubation	5min after intubation

BP				
Pulse rate				
SpO2				

- **EtCo2:**

After peritoneal inflation	After peritoneal deflation

- **Ease of Intubation:**

EASY	DIFFICULT

- **Success Rate:**

Intubated	Failed to intubate

- **Number of attempts:**
- **Time taken to intubate:**
- **Gastric Distension:**

0	1	2	3	4	5	6	7	8	9	10

- **Sore Throat:**

YES	NO

- **Laryngeal stridor:**

OCCURED	NOT OCCURED

- **Blood stain in the airway device used:**

YES	**NO**